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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,774	07/25/2001	Manaud Pierre Frederic De Raspidé	PC10915A	5154

28880 7590 11/18/2005
WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/912,774	Applicant(s) DE RASPIDE ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10,13,14,16-25,27-37,41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 27-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-10,13,14,16-25,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of requests for continued examination under 37 CFR 1.114 and extension of time, amendment, remarks, all filed 10/21/05.

New Claims Identified as Original Claims:

In the Office action mailed 05/23/2005, claims 27-37 were identified as being submitted as new original claims. Claims 27-37 presented on 03/16/04 were method claims. The claims 27-37 submitted on 2/22/05 were composition claims and were thus withdrawn from examination as drawn to different invention from the invention that was originally presented for examination.

Applicants are silent on the withdrawal of those claims from examination.

Examiner respectfully requests applicants to respond to the above non-elected claims.

Claims 27-37 are withdrawn from examination as drawn to non-elected claims.

Therefore, claims 1, 2, 5-10, 13, 14, 16-25, 41 and 42 are examined.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 10/21/05 has been entered.

Drawings

Applicants acknowledge the objection to the drawings and indicate that corrected drawing will be filed upon identification of allowable subject matter. However, the objection

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will not be held in abeyance and the objection will be made in all office actions until applicants comply with the drawing requirements.

Claim Rejections - 35 USC § 112

Original claims 32-37 filed 03/16/2004 were the claims that were rejected. However, applicants have not reintroduced these claims for examination and thus the rejection is withdrawn because those claims were replaced with new claims that were identified as original claims.

New Matter

1. Claims 1, 2, 5, 6-10, 13, 14 and 16-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description of a first layer containing eletriptan in the disclosure. There is no exemplification of how that first layer containing eletriptan is formed. The recitation of first layer has no support in the specification as originally filed. "First layer" is new matter.
2. Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 41 directs that the eletriptan be contained in the core, but amended claim 1 recites that the core/seed is coated with a layer containing eletriptan. It is not clear what the invention is with respect to the eletriptan core and the core coated with a layer of eletriptan.

Claim 42 is confusing because 42 (a) is not clear. Clarification is required.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1 under 35 U.S.C. 102(e) as being anticipated by Cherukuri et al. (US 2002/0044962) is withdrawn because Cherukuri is not prior art since Cherukuri was filed 10/19/2001 and does not have the benefit of US 6,555,145 filed 06/06/2000 since the US 6,555,145 does not support the disclosure of eletriptan.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1, 2, 5, 6-10, 16-25, 41 and 42 under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 00/06161) in view of Cherukuri et al. (US 2002/0044962) is withdrawn because as stated above, Cherukuri is not prior art for the application.

5. Claims 1, 2, 5, 6-10, 13, 14, 16-25, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 00/06161) in view of Stevens et al. (US 5,112,621).

Jackson discloses the use of eletriptan for treating migraine recurrence, in a dual-, sustained-, delayed-, controlled-, or pulsed-release dosage form (abstract). Jackson discloses that both the hydrobromide salt and the hemisulfate form of eletriptan are known in the art (page 1, lines 9-13). Jackson specifically discloses that the formulation of their invention can be in a pulsed-release form, including the sigmoidal releasing pellets discussed in US 5,112,621.

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Stevens (referred to immediately above) discloses a sustained release pharmaceutical composition, which comprises microparticles comprising an active agent (abstract). Furthermore, said microparticles are coated with a coating mixture comprising ethyl cellulose and an acrylic resin made of a polymer of acrylic and methacrylic ester, wherein the resin contains trimethylammonium methacrylate chloride (abstract). Stevens also discloses that the uncoated microparticles may comprise excipients such as a diluent and a binder. The diluent may be microcrystalline cellulose, and the binder may be hydroxypropylmethyl cellulose (column 1, line 61 - column 2, line 2). Additionally, a plasticizer, such as triethyl citrate, may be included (column 2, line 8). Stevens also discloses that the microparticulates can be in a unit dosage form, such as a hard gelatin capsule (column 1, lines 49-51).

One of ordinary skill in the art would have been motivated to combine the teachings of Jackson and Stevens as this is precisely what is discussed in the Jackson et al. reference. This reference clearly refers to the Stevens reference as a teaching when a formulation with sigmoidal release is desired.

Applicants' argument with respect to Cherukuri is moot because Cherukuri is not prior art.

Applicants' argument with respect to Jackson in view of Cherukuri is moot because Cherukuri is not prior art.

6. Applicants' arguments with respect to Jackson in view of Stevens filed 10/21/05 have been fully considered but they are not persuasive.

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Regarding applicants statement that a coated sugar core cannot be used is Jackson is not persuasive because applicants are relying on limitations that are not in the claims. Hence the declaration is not commensurate with the scope of the claims that do not recite sugar cores.

Controlled release is dictated by the excipients incorporated with the active agents in a composition and Stevens discloses those excipients and Jackson specifically provides directions to use the teachings of Stevens.

Request:

Applicants are respectfully requested to provide amendment that complies with the claim amendment procedure. Claims 27-37 are withdrawn from consideration and should not be used to replace originally filed claims. These claims may be presented as new claims, but since these are withdrawn as directed to non-elected claims because these claims differ in scope from the originally filed claims, they cannot be considered with the originally filed claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read 'Blessing Fubara', is written over the printed name.